Louisiana Office of Public Health Laboratories	
Test Name	Amplified Nucleic Acid Test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	87591, 87491
Synonyms	CT/GC, Gonorrhea/Chlamydia, or Gen-Probe test
Brief Description of Test	The APTIMA Combo 2 Assay is a target amplification nucleic acid probe test for the in vitro qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using the TIGRIS DTS Automated Analyzer
Possible Results	CT Pos — Positive for CT rRNA CT Neg — Presumed negative for CT rRNA CT Equiv — Indeterminate, a new specimen should be collected Invalid — Indeterminate, a new specimen should be collected GC Pos — Positive for GC rRNA GC Neg — Presumed negative for GC rRNA GC Equiv — Indeterminate, a new specimen should be collected Invalid — Indeterminate, a new specimen should be collected
Reference Range	Not Detected
Specimen Type	Endocervical swab, male urethral swab, pharyngeal (throat) swab, rectal swab and urine
Specimen Container(s):	Aptima Unisex swab and Aptima Urine collection kit - Contact Office of Public Health Laboratory Baton Rouge to obtain kits.
Minimum volume accepted:	Liquid levels in urine specimen must fall between the two black indicator lines on the urine transport tube label.
Collection Instructions	Label specimen with Patient Name and a 2nd Unique Identifier such as a chart number or medical record number. DOB is not considered unique. Complete a STD/HIV Lab Form for each specimen or order test in StarLIMS. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date and time of collection, specimen source, test requested, submitter's name, address, fax and contact number. Additional information regarding patients' address is requested. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.

Endocervical Swab Specimens

- Remove excess mucus from the "cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with the red printing). DISCARD THIS SWAB.
- Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal.
- Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
- Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- Immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing contents. Cap the tube tightly.

Male Urethral Swab Specimens

- The patient should not have urinated for at least 1 hour prior to sample collection.
- Insert the specimen collection swab 2 to 4 cm into the urethra.
- Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.
- Withdraw the swab carefully.
- Immediately place the specimen collection swab into the transport tube. Carefully break the swab against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing contents. Cap the tube tightly.

Male and Female Urine Specimens

- The patient should not have urinated for at least 1 hour prior to specimen collection.
- Direct patient to provide a first-catch urine into a urine collection cup free of any preservatives
- Female patients should not cleanse the labial area prior to providing the specimen.
- Transfer 2mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube. Cap the tube tightly.

Male and Female Rectal Swabs

- Gather collection materials and use the small APTIMA testing swab, not the larger cleansing swab.

	• Insert the swab approximately 3 – 5 cm into the rectum and rotate against the rectal wall several times (at least 3 times). • Swabs that are grossly contaminated with feces should be discarded and the collection repeated. • Carefully remove the swab, and insert the swab into the APTIMA transport tube. • Break off the swab at the score line and discard the top portion of the swab shaft; use care to avoid splashing contents. Cap the tube tightly. **Male and Female Throat Swab Collection** • Gather collection materials and use the small APTIMA testing swab, not the larger cleansing swab. • Using a tongue depressor, insert the swab and vigorously rub the tonsils and the posterior pharynx. • Carefully remove the swab, not touching any area of the mouth. • Insert the swab into the APTIMA transport tube and break off the swab at the score line. • Cap the tube tightly.
Storage and Transport Instructions	The samples must be stored at 2°C to 30°C until tested. This sample range must be maintained during transport of the samples to the laboratory. Swab specimens must be assayed with the APTIMA Assays within 60 days of collection and urine specimens within 30 days of collection. If longer storage is needed, store at -20°C to -70°C for up to 90 days after collection. Prevent cross-contamination by packaging in the multi-compartment bubble wrap pouches or put each specimen into a separate leak-proof specimen bag before placing in coolers for shipment.
Causes for Rejection	• Two swabs in specimen tube • White swab in specimen tube • Insufficient urine specimen volume received (liquid levels for urine specimens must be between the two black indicator lines on the urine transport tube label) • Overfilled urine specimen tube • Specimen collected from the eye • Urine specimen received in the laboratory more than 30 days after collection date; swab sample received in the laboratory more than 60 days after the collection date. • No swab in specimen tube • Inadequate sample, patient, or submitter information • Specimen **collected** in expired transport media. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility. Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package

	insert, are valid for testing even if the expiration date on the collection tube has passed. • Specimens tubes not separated during transport
Limitations of the Procedure	A negative test result does not exclude the possibility of infection because tests results may be affected by improper specimen collection, handling, transport, technical error, specimen mix-up or concurrent antibiotic therapy. Additionally, the concentration of organisms may be below the sensitivity of the test. Results from the Gen-Probe Aptima System should be used in conjunction with other clinical data available to the clinician. If the clinical indication strongly suggests infection, additional specimens should be collected for further testing. Identification methods can yield false positive results. In those instances additional testing is recommended. The performance has not been evaluated in adolescents less than 16 years of age.
Interfering Substances	Excessive temperatures, Patient on antibiotic therapy, Inappropriate collection techniques, see package inserts from Gen-Probe APTIMA Combo 2 Collection Kits.
References	• Center for Disease Control, National Center or HIV, STD, TB Prevention, Division of Sexually Transmitted Disease • Gen-Probe Incorporated, San Diego, California, package inserts
Additional Information	None
Release Date	04/14/2016
Warning: If you have printed a copy of this information please be advised that the Louisiana Office of Public Health Laboratories website and methods are updated on a regular basis. Please check the on-line version of this document to ensure you are relying on the most recent release.	